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News and Views that Matter to Dermatology

Abbott Withdraws Briakinumab Approval Application

By: ELIZABETH MECHCATIE, Skin & Allergy News Digital Network

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Abbott Laboratories, the manufacturer of briakinumab, a monoclonal antibody that has been under review at the Food and Drug Administration as a treatment for psoriasis, has withdrawn the application for approval in the United States and in Europe, according to a filing with the U.S. Securities and Exchange Commission on Jan. 14.

"Following feedback from regulatory authorities indicating the need for further analysis and the potential for additional studies, the company plans to evaluate the next steps for briakinumab, including resubmission at a later date," the filing stated.

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Briakinumab is an anti-IL-12/23 monoclonal antibody, also known as ABT-874, which targets the IL-12/23 proteins that are linked to inflammation and is the second biologic in this class to complete phase III trials for treating plaque psoriasis, according to Abbott. In four studies presented at the European Association of Dermatology and Venereology, skin clearance rates among patients with moderate to severe chronic plaque psoriasis were greater among those treated with briakinumab than among those who were treated with etanercept, methotrexate, or placebo, Abbott reported in October.

The company did not issue a statement regarding the withdrawal of the application, or provide any details as to why the application is being withdrawn.

In an interview, Dr. Alan Menter, chairman of the division of dermatology at Baylor University Medical Center in Dallas, did not speculate as to why the applications were withdrawn. But he pointed out that the FDA is very "risk averse" and referred to information in the public domain, namely, cases of major adverse cardiovascular events (MACE) associated with briakinumab. In January 2010, the MACE events resulted in the requirement that patients with more than one risk factor for heart disease discontinue the long-term clinical study.

While briakinumab is a "great drug" that has been associated with the most clinically significant results ever seen with a systemic or biologic psoriasis drug, Dr. Menter said that the mechanisms behind the potential short- and long-term risk for MACE needs to be evaluated. If briakinumab is reducing inflammation in psoriasis, it would also be expected to possibly reduce adverse coronary events.

There were a few cases of MACE among patients treated with ustekinumab, and none among those on placebo, in early phase II studies. However, apparently there were no differences in long-term studies, so it is unclear whether this will be an issue with ustekinumab, he said.

Dr. Menter has conducted research for, and is an advisor and consultant to Abbott, but has no stock in the company. He has also been an investigator for ustekinumab studies.

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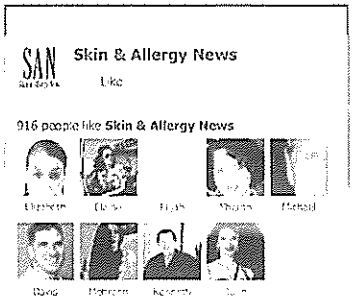

Question of the Week

Do you regularly screen your psoriasis patients for comorbidities that could increase their risk for cardiovascular disease and other problems?

- Always
- Not Regularly
- Never

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calendar

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Feb 2 - 5 New Orleans, LA	American Academy of Dermatology Annual Meeting/Managing Medically Annual Meeting
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Feb 3 New Orleans, LA	15th Annual Meeting of the Skin Cancer
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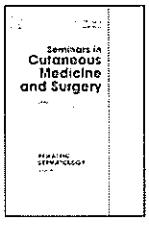

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